REMARKS/ARGUMENTS

Claims 1-4 are pending in the instant application. Claims 1-3 stand rejected under 35 USC § 103(a) as being unpatentable over United States Patent No. 3783291 to Czaplinski in view of United States Patent No. 3369121 to Bruno and United States Patent No. 3774035 to Litt. Claim 4 stands rejected under USC § 103(a) as being unpatentable over Czaplinski, Bruno and Litt, and in further view of Riely. The application has been amended. The claims have been amended. Claims 1 and 4 have been amended to more particularly claim the present invention. New claim 5 has been added. Applicants respectfully submit that none of the amendments constitute new matter in contravention of 35 U.S.C. §132. Reconsideration is respectfully requested.

Claims 1-3 stand rejected under 35 USC § 103(a) as being unpatentable over United States Patent No. 3783291 to Czaplinski in view of United States Patent No. 3369121 to Bruno and United States Patent No. 3774035 to Litt. This rejection is respectfully traversed.

The present invention is directed to a radioisotope generator. The generator includes a shielded chamber within which is located an isotope container housing a radioactive isotope. The shielded chamber includes first and second fluid connections to opposing ends of the isotope container and a fluid conduit extending from each of the first and second fluid connections to a fluid inlet and a fluid outlet, respectively. The fluid inlet comprises a single spike having a spike body with a substantially circular cross-section so that the spike body is adapted to penetrate the rubber seal of a vial. The spike body further defines a first bore

extending from a first aperture adjacent the tip of the spike to a fluid connection with the fluid conduit. The spike body also defines a second bore extending from a second, separate aperture in the spike body to a filtering air inlet. The spike body incorporates a barrier filter in the second bore which will allow air to pass towards an eluent bottle while preventing liquid flowing into the second bore and out of the filtering air inlet.

Czaplinski discloses a device for producing a fluid containing a radioactive constituent having a shielded housing for a container with the radioactive fluid. At each end of the housing is a pierceable septum. A fluid conduit extends from the bottom of the housing and runs out to a pierceable fixture on a frustroconical stand on which the housing rests. The contents of an eluent bottle is placed in fluid communication with the container by means of a double-pointed spike assembly which pierces into both the bottle and the container. The spike includes two lumens, one for communicating between the bottle and the container, the other for venting the contents of the bottle and allowing fluid flow into the container. In order to vent the contents of the bottle the spike assembly further includes an elongate venting tube extending from the second lumen to a position extending above the highest level of the inverted bottle. The elevation of the free end of the venting tube is required to prevent the contents of the eluent bottle from simply draining out the venting lumen.

Bruno discloses the shielded housing of Czaplinski device.

Litt discloses another system for collecting a radioactive eluate. Like Czaplinski, Litt provides an elongate venting tube which extends higher than the vent and drain needles which pierce an eluent bottle. Litt further discloses an antibacterial plug having a sterile barrier being placed at the high end of the vent tube.

Applicants respectfully submit that the present invention is clearly patentably distinct from the cited references. The present invention provides a dual-lumen spike which also contains a barrier filter within the spike body. As the barrier filter prevents liquid from leaking out the air inlet on the spike body while allowing air to pass from outside the spike body and through the second bore, the present invention obviates the need for an elongate vent tube which extends above the fill line of the supported eluent bottle and the need to clean the vent tube of any eluent fluid which may collect therein.

Neither Czaplinski, nor Bruno, nor Litt, either alone or in combination, disclose, teach or suggest a dual lumen spike body which incorporates a barrier filter therein to thereby obviate the need for an elongate venting tube. As a result, Applicants respectfully submit that the present invention is patentably distinct thereover. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 4 stands rejected under USC § 103(a) as being unpatentable over Czaplinski, Bruno and Litt, and in further view of Riely. This rejection is respectfully traversed.

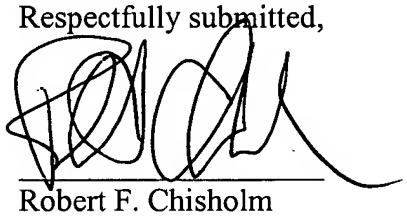
Riely discloses a gas venting device having a Y-shaped flow channel. A single filter disc spans the junction of the flow channel. The disc includes a portion which is hydrophobic and a portion which is hydrophilic such that each segment occupies one-half of the disc. In this arrangement, gas will vent through one arm of the Y channel, i.e., the arm protected by the hydrophobic half of the disc, and fluid will flow through the other arm of the Y channel, i.e., the arm protected by the hydrophilic half of the disc. Riely achieves the two-part function of the disc by treating only one-half of the disc so as to be hydrophobic. Riely does disclose that the starting disc may be formed from polytetrafluoroethylene.

The Examiner cites Riely for disclosing a bacterial barrier which could be incorporated at the end of the venting tube of Litt. Applicants respectfully submit that such a combination fails for two reasons. First, a fair reading of Riely would provide a disc which on one-half would pass liquid and on the other half would pass gas. Such a disc in the present invention would be inoperative as the disc would fail to act as a barrier to the eluent liquid. Second, assuming *arguendo* that Riely fairly suggested the use of a proper barrier material, this barrier material would be located at the distal end of a vent tube extending above the fluid line of the eluent bottle and not within the body of the dual-lumen spike itself. As a result, Applicants respectfully submit that Riely fails to correct the deficiencies of Czaplinski, Bruno, or Litt. Therefore, as neither Riely nor the other references disclose, teach, or suggest a dual-lumen spike incorporating a barrier filter material therein, the present invention is patentably distinct thereover. Reconsideration and withdrawal of the rejection are respectfully requested.

In view of the amendments and remarks hereinabove, Applicants respectfully submit that the instant application, including claims 1-5, is in condition for allowance. Favorable action thereon is respectfully requested.

Any questions with respect to the foregoing may be directed to Applicant's undersigned counsel at the telephone number listed below.

Respectfully submitted,



Robert F. Chisholm
Reg. No. 39,939

Amersham Health, Inc.
101 Carnegie Center
Princeton, NJ 08540
Phone (609) 514-6905

I:\IP\Response to Office Action\PZ\PZ0218(DRAFT)[1].doc